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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,843	07/28/2003	Leonard S. Schultz	6971.02	5820

7590 01/13/2010  
David E. Bruhn  
DORSEY & WHITNEY LLP  
Intellectual Property Department  
50 South Sixth Street, Suite 1500  
Minneapolis, MN 55402-1498

EXAMINER
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YABUT, DIANE D

ART UNIT	PAPER NUMBER
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3734

MAIL DATE	DELIVERY MODE
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01/13/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/628,843	<b>Applicant(s)</b> SCHULTZ, LEONARD S.	
	<b>Examiner</b> DIANE YABUT	<b>Art Unit</b> 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 10/07/2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 29-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                                                     |                                                                                         |
|-------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                                | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>09/10/2009</u> . | 6) <input type="checkbox"/> Other: _____                                                |

### DETAILED ACTION

This action is in response to applicant's amendment received on 10/07/2009.

The examiner acknowledges the amendments made to the claims.

#### *Information Disclosure Statement*

1. The information disclosure statement (IDS) submitted on 09/10/2009 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

#### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 29, 31, and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by **Lemelson** (U.S. Patent No. **4,900,303**).

In Figures 7-8 and 14 Lemelson discloses providing a “porous” plug **109**, **109A**, or **159** being configured and dimensioned to substantially completely occlude flow through a lumen (“body duct”; abstract), the plug having an outer surface in which a plurality of openings are formed wherein the openings are spaced from one another and having a shape (such as a cylindrical shape) suitable for allowing flow of a biological bonding agent therethrough, advancing the plug to a delivery site with a delivery

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instrument ("piston") **158** with wire shaft **162** (Figure 14; col. 14, lines 19-47) that is detachably coupled to the plug for delivering the plug to a selected location in the lumen, the plug entering the lumen before the delivery instrument enters the lumen, and an access catheter **160** positioned within the delivery instrument for injecting a biological bonding agent ("adhesive-medication mixture", col. 12, lines 47-65) through the openings, wherein upon delivery of the biological bonding agent to the openings by the access catheter, the biological bonding agent extrudes through the plurality of openings to bind the plug to an interior wall of the lumen ("adhesive may also be coated on or impregnated throughout the [plug] to be disposed" so that it may "be slowly dispensed therefrom to the body duct"; col. 12, lines 47-65), and withdrawing the delivery means from the plug.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 30 and 32-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Lemelson** (U.S. Patent No. **4,900,303**) in view of **Wallace** (U.S. Patent No. **6,585,754**).

Lemelson disclose the claimed invention, except for the bonding agent being a biphasic material comprising a biosorbable or shape memory material.

Wallace teaches the use of biphasic material and biosorbable materials (col. 4, lines 48-57) and shape memory materials (col. 4, lines 41-45), wherein the biosorbable and shape memory materials are biphasic. It would have been obvious to one of ordinary skill in the art to have the bonding agent comprise shape memory material, as taught by Wallace, to Lemelson, in order to provide greater tissue ingrowth and therefore a more stable occlusion in the body lumen (col. 4, lines 15-17), and since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use.

### ***Response to Arguments***

5. Applicant's arguments filed 10/07/2009 have been fully considered but they are not persuasive.
6. Applicant argues that the plug **159** in Lemelson does not enter the lumen before the delivery instrument **160**, but rather enters simultaneously as seen in Figure 14. However, the currently cited delivery instrument is now the ("piston") **158** with wire shaft **162**, wherein the plug enters the lumen before the delivery instrument, or is distal to the delivery instrument, and the access catheter is now cited as **160**, and therefore Lemelson reads on this limitation.
7. Applicant also argues that the porous implant of Lemelson that is impregnated with an adhesive-medication mixture which may be dispensed through the pores does not have the claimed outer surface having a plurality of openings formed to enable extrusion of adhesive through the openings. The examiner disagrees. In order for the

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adhesion-medication mixture to be dispensed from the porous plug, its outer surface must have openings which enable the extrusion or flow through the porous cells and dispensing of the mixture, and therefore the plug of Lemelson reads on this limitation.

### ***Conclusion***

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/  
Examiner, Art Unit 3734

/Todd E Manahan/  
Supervisory Patent Examiner, Art Unit 3734